REMARKS/ARGUMENT

A Notice of Appeal was filed September 4, 2008, making the Appeal Brief due November 4, 2008. A Petition for an Extension of one month to file the Appeal Brief is filed herewith, making the new deadline for reply December 4, 2008. Applicants have filed concurrently herewith an RCE, thereby withdrawing this application from appeal. Since the RCE and the instant Amendment have been filed by the extended deadline of December 4, 2008, the reply is timely.

As an initial matter, the rejection of claims 12-15, 18, 25-31, 41-44, 47, 54-59, 69-72, 75, 82-87, 92, 95, 102, 104-107, 112, 115, 122, 124-127, 132, 135, 142-145 and 157-161 has been rendered moot by cancellation of those claims.

Support for new claims 165-166 is found at [0067] of US2002/0006443, which is the published version of the instant application. Likewise, support for new claim 167 is found at [0061] of the same publication, while support for new claim 168 is found, e.g., at [0138]. Accordingly there is no issue of new matter.

Two independent claims remain, namely claims 1 and 164. Claims 2, 29, 156 and 165-167 all depend from claim 1, and claims 165-168 also depend form claim 164. Both claims 1 and 164 have been amended to recite that the crystalline highly soluble salt form of the drug is "other than the crystalline hydrochloride salt." Since Miyajima's drug form (NZ-105) is a hydrochloride salt, both claims 1 and 164 exclude NZ-105. Accordingly, this §102 rejection of claims 1-2 and 29 is submitted to be overcome.

As to the §102 rejection of claims 1-2, 29 and 164 as being anticipated by Dunn, Dunn's drug Verapamil is not poorly soluble in water as argued by the Examiner, but rather is highly water-soluble with a solubility of 100g/mL (column 2, lines 65-67; and see column 1,

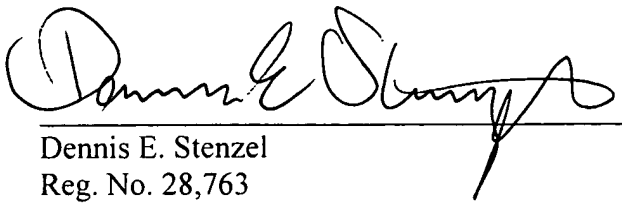
lines 14-21). Claims 1-2, 29 and 164 all recite that the drug alone has an aqueous solubility of "less than about 1 mg/mL" and Dunn's drug is about 100,000 times more soluble. Accordingly those claims are also readily distinguishable from Dunn, and so the §102 rejection is submitted to be overcome.

Claims 1-2, 129 and 164 also stand rejected under §102 as being unpatentable over Okada. But at best Okada formulates his drug-containing cores by forming a solution of drug, hydroxypropyl cellulose (HPC) and spraying that solution onto spherical sugar prills. See Examples 1-12 of Okada. HPC is not one of the polymers claimed by applicants. (Okada's only mention of HPMCAS is as a possible membrane layer coating of the drug-containing core. See column 3, lines 36-39 and column 4, lines 11-13 and 21-22.) Accordingly, this rejection is also submitted to be overcome.

Finally, claims 1, 156 and 164 stand rejected under §102 as being unpatentable over Bymaster. But Bymaster merely coats HPMCAS onto a drug-containing dosage form. See column 10, last paragraph. This results in a dosage form that does not comprise drug and polymer present as particles in a dry physical mixture, as claimed by applicant. This §102 rejection is therefore also submitted to be overcome.

Favorable reconsideration is respectfully solicited.

Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dec 4 '08
Date

Dennis E. Stenzel